

II. Supplemental Information Disclosure Statement

Applicants submit, concurrently with this Amendment, a Supplemental Information Disclosure Statement that complies with 37 C.F.R. § 1.98(a)(2) and copies of the cited references as attachments thereto. Consideration of these references and acknowledgment by initialing the Form SB/08 is respectfully requested.

III. Status of the Drawings

The Drawings have been objected for including inadequate margins. Applicants submit herewith a replacement sheets with Figs. 1C, 7A, 11, 13, and 16 in order to correct the size of the margins, as requested by the Examiner. Based on the foregoing, Applicants respectfully request the above objection be withdrawn.

IV. 35 U.S.C. § 112 Rejection

Claims 23-26 have been rejected under 35 U.S.C. § 112, first paragraph. The Examiner states that the Specification does not convey that the inventors had possession of the claimed invention (Office Action dated February 23, 2005, pages 3-5). Applicants respectfully traverse this rejection, and reconsideration is respectfully requested.

Claims 23-26 have been amended to depend on claim 31, which states that the model described in claim 17 includes viscoelastic properties of second order components, e.g., osteons, trabeculae, or lamellae, that are assigned based on experimental determinations. The experimental determinations include the steps of selecting a plurality of subject bones of a specified type, dividing each of the subject bones into a plurality of second order samples, wherein each sample corresponds to a location within the specified macroscopic region of each subject bone, evaluating one or more viscoelastic properties of at least one second order component of each sample, and aggregating the evaluations.

is sufficient that the claimed steps are performed, or that the elements of the claimed system are present in relation to each other, as claimed.

A system or method implemented "by hand" is patentable. That some steps encompass calculations or comparisons does not mandate the use of a computer or implementation by hardware and software.

In *Alco Standard Corp. v. TVA*, 808 F.2d 1490, 1496 (Fed. Cir. 1986), the court held that a process that is capable of being performed by a person or by a machine is patentable. Appellants contended that steps of "correlating and combining" data were "merely mental processes, and therefore, unpatentable." *Id.* at 1496. However, the court stated that "[u]nder the meaning of correlating used in the patent, these steps may be performed either by a person or by a machine... The inclusion in a patent of a process that may be performed by a person, but that also is capable of being performed by a machine is not fatal to patentability" *Id.*, citing *Diamond v. Diehr*, 450 U.S. 175 (1981).

Furthermore, a claim that has a practical application in the technological arts is statutory (MPEP § 2106, paragraph IV.B.2(a), page 2100-15). The Examiner states that (emphasis added):

To be statutory, the utility of an invention must be within the technological arts. *In re Musgrave*, 167 USPQ 280, 289-90 (CCPA, 1970). The definition of "technology" is the "application of science and engineering to the development of machines and procedures in order to enhance or improve human conditions, or at least to improve human efficiency in some respect." (Computer Dictionary 384 (Microsoft Press, 2d ed. 1994)). (Office Action dated February 23, 2005, page 10.)

Clearly the invention provides procedures to enhance and improve human conditions, i.e., modeling bone to assess bone deformations, to compute stresses and strains due to specific forces acting on bone and to predict forces that do or do not cause viscous effects or elastic or plastic bone deformations.

The MPEP also states that an example of a type of claimed statutory process is "[a] digital filtering process for removing noise from a digital signal comprising the steps of calculating a mathematical algorithm to produce a correction signal and subtracting the correction signal from the digital signal to remove the noise" (MPEP § 2106, paragraph IV.B.2(b)(ii), page 2100-18). Clearly, this exemplary statutory process sets forth a mathematical algorithm including calculations, but does not set forth any machine, e.g., computer hardware or software components.

A machine or method claim is statutory when the machine or method, as claimed, "produces a concrete, tangible and useful result" (MPEP § 2106, paragraph IV.B.2(b)(ii), page 2100-18, citing *AT&T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352, 1358 (Fed. Cir. 1999) and *State Street Bank & Trust Co. v. Signature Financial*, 149 F.3d 1368, 1373 (Fed. Cir. 1998)). The invention set forth in the pending claims includes a transformation of data to produce a useful, concrete, and tangible result. For example, a transformation of data occurs when the viscoelastic properties of the second order components are used to determine a viscoelastic property of the first order region of macroscopic bone. This transformation of data produces a useful, concrete, and tangible result which is the properties of the first and second order components. These properties are used to study or predict the behavior of the bone, e.g., when it is subject to an external force. The predictions of the behavior of bone can be used, for example, to improve the fitting of implants. The behavior of the bone subject to the external force can also be used to study deformation and fracture in the bone.

For the aforementioned reasons, the subject matter of the claims is statutory with or without the recitation of computer hardware or software components.

Based on the foregoing, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn, and reconsideration is respectfully requested.

does not disclose or suggest a model in which the second order components, e.g., osteons, trabeculae, and lamellae, are non-homogeneous or a model that incorporates a hierarchical structure in which the viscoelastic properties of second order components are used to help predict the behavior of a first order macroscopic region of bone.

The Office Action also contends that Wolfinbarger discloses mucopolysaccharide content. However, as noted above, like Crolet, Wolfinbarger shows only that various properties can be measured; they do not teach or suggest incorporating viscoelastic properties into a model of bone, nor measuring them for that purpose.

D. Crolet, Ascenzi '99, Lakes, Carter, Wolfinbarger, and Ascenzi '93 (Claims 5 and 6)

Claims 5 and 6 have been rejected as being unpatentable over Crolet in view of Ascenzi '99 and Lakes and further in view of Carter, Wolfinbarger, and Ascenzi, "The torsional properties of single selected osteons," October 1993 ("Ascenzi '93"). Applicants respectfully traverse this rejection, and reconsideration is respectfully requested.

Claims 5 and 6 have been amended to depend from claim 1 and state that the viscoelastic property is selected from the group consisting of an angle-of-twist as a function of torque, osteon hydroxyapatite content, strain rate, or time. Claim 22 also recites this feature of the invention.

The Office Action contends that Crolet, Ascenzi '99, Lakes, Carter, and Wolfinbarger teach the bone model set forth in claim 3, from which claims 5 and 6 previously depended. However, as noted above, these references do not disclose or suggest a model in which the second order components, e.g., osteons, trabeculae, and lamellae, are non-homogeneous or a model that incorporates a hierarchical structure in which the viscoelastic properties of second order components are used to help predict the behavior of a first order macroscopic region of bone.

The Office Action also contends that Ascenzi '93 discloses angle-of-twist as a function of torque, strain rate, or time. However, Ascenzi '93 shows only that torsional properties of osteons

can be measured; it does not teach or suggest incorporating angle-of-twist as a function of torque, strain rate, or time into a model of bone, nor measuring it for that purpose.

E. Crolet, Carter, Wolfinbarger, and Ascenzi '93 (Claims 22 and 23)

Claims 22 and 23 have been rejected as being unpatentable over Crolet in view of Carter and further in view of Wolfinbarger and Ascenzi '93. Applicant respectfully traverses this rejection, and reconsideration is respectfully requested.

Claim 23 has been amended to depend from claims 17, 30, and 31 and discloses incorporating angle-of-twist as a function of torque. Claim 22, as described above, recites that the viscoelastic property is angle-of-twist as a function of torque, osteon hydroxyapatite content, strain rate, or time. The claim has been amended to disclose the experimental steps that are taken to determine the angle-of-twist as a function of torque based on a torque vs. angle-of-twist curves that are determined from torsional testing of various samples of bone.

The Office Action contends that Crolet, Carter, and Wolfinbarger teach the bone model recited in the claims and that Ascenzi '93 discloses angle-of-twist as a function of torque. However, as noted above, these references do not disclose or suggest a model in which the second order components, e.g., osteons, trabeculae, and lamellae, are non-homogeneous or a model that incorporates a hierarchical structure in which the viscoelastic properties of second order components are used to help predict the behavior of a first order macroscopic region of bone. Furthermore, Ascenzi '93 does not teach or suggest incorporating angle-of-twist as a function of torque into a model of bone, nor measuring it for that purpose using data derived from experiments using samples of bone.

F. Crolet, Ascenzi '99, Lakes, and Ascenzi '93 (Claim 16)

Claim 16 has been rejected as being unpatentable over Crolet in view of Ascenzi '99 and Lakes and further in view of Ascenzi '93. Applicant respectfully traverses this rejection, and reconsideration is respectfully requested.

Ascenzi '93 discloses that fractures occur when torque is applied to experimental bone samples (Ascenzi '93, page 881, column 1, paragraph 4, to column 2, paragraph 2). However, Ascenzi '93 does not disclose a bone model for predicting deformation and fracture. Ascenzi '93 only hypothesizes on the location of fracture; it does not disclose the steps of calculating stress and strain distributions and making comparisons to determine where fracture occurs in a bone model.

I. Crolet, Ascenzi '99, Lakes, Copland, and Agrawal (Claim 19)

Claim 19 has been rejected as being unpatentable over Crolet in view of Ascenzi '99 and Lakes and further in view of U.S. Patent No. 6,333,313 to Copland ("Copland") and U.S. Patent No. 5,947,893 to Agrawal et al. ("Agrawal"). Claim 19 has been canceled without prejudice and the rejection is moot.

J. Crolet, Carter, Wolfinbarger, Hamamoto, and Ascenzi '97 (Claim 26)

Claim 26 has been rejected as being unpatentable over Crolet in view of Carter and Wolfinbarger and further in view of U.S. Patent No. 5,732,469 to Hamamoto et al. ("Hamamoto") and Ascenzi, "X-ray diffraction on cyclically loaded osteons," August 1997, ("Ascenzi '97"). Applicant respectfully traverses this rejection, and reconsideration is respectfully requested.

Claim 26 depends from claim 31, 30, and 17 and has been amended to state that the viscoelastic property of the second order components is modified based on collagen-bundle directions of the selected bone, the method further comprising the step of determining collagen-bundle directions of the samples using circularly polarizing light microscopy, confocal microscopy or X-ray diffraction of the samples.

The Office Action contends that Crolet, Carter, and Wolfinbarger teach the bone model recited in the claims. However, as noted above, Crolet, Carter, and Wolfinbarger do not disclose or suggest a model in which the second order components, e.g., osteons, trabeculae, and

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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